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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/812,532 | 03/20/2001 | David Allen Schul | 8003 | 2563 |

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| EXAMINER |
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JIANG, SHAOJIA A

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| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 01/29/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/812,532 | SCHUL ET AL. |
| | Examiner | Art Unit |
| | Shaojia A. Jiang | 1617 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 04 January 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) 42-50 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-41 and 51-56 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

Applicant's remarks and election with traverse of the invention of Group II, Claims 13-37, 41, and 54-56 in Paper No. 6, submitted January 4, 2002 is acknowledged.

The traversal is on the ground(s) that inventions I and II are clearly shown to be disclosed as capable of use together. This is found persuasive as to Groups I and II, drawn to a sterol ester composition and a food product comprising the same sterol ester composition. Therefore, the Requirement for Restriction is modified as to Groups I and II. The invention of Group I is herein combined with the invention of Group II.

The traversal is on the ground(s) that inventions I and II drawn to process claims are not independent or distinct. This is found persuasive as to Groups III and IV, drawn to methods for the preparation of sterol ester compositions herein and methods for the preparation of food products herein. Therefore, the Requirement for Restriction is modified as to Group III and IV. The invention of Group III is herein combined with the invention of Group IV.

However, the traversal is on the ground(s) that since "no specific solvents or catalysts are set forth in the process claims", there is no burden for search Group I or Group II drawn to product made and Group III or IV drawn to process of making. This is not found persuasive. As discussed in the Restriction Requirement (October 10, 2001), the inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process

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(MPEP § 806.05(f)). In the instant case, Group III or IV read on methods for the preparation of sterol ester compositions herein and food products comprising the same sterol ester compositions by interesterification using catalyst. According to the instant disclosure, sodium methylate catalyst and methanol as solvent are employed in the instant claimed methods (see the specification herein page 7 lines 23-24 and 26). One of ordinary skill in the art would recognize that other catalyst such as sodium ethylate and other solvent such as ethanol can be used in the instant methods. Moreover, according to Applicant's admission regarding the prior art (see the specification herein page 7-22), methods for preparing sterol esters with fatty acids are known in the art. Therefore, Inventions of Groups I-II; and III-IV are seen to be independent and distinct each from other and present an undue burden on the Office for the search all inventions. Note that the search is not limited to patent files.

Since it is found persuasive that Groups I and II are drawn to a sterol ester composition and a food product comprising the same sterol ester composition and the search for all of these inventions is not an undue burden, claims 1-41 and 51-56 will be examined on the merits herein. Applicant's election of Group I will be taken an election of the invention of Groups I-II. The requirement between Groups I-II; and III-IV is therefore made FINAL.

Therefore, claims 42-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expressions for example "a free sterol level of less than 10%" in claim 51 render claims 51-56 indefinite. The expressions "a free sterol level of less than 10%" are not understood. Therefore, the scope of claims is indefinite as to the composition encompassed thereby.

Claims 1-40 and 51-56 contains the trademark/trade name MUFAs, SFAs, and PUFAs. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe particular fatty acids herein and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-41 and 51-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miettinen et al. (5,502,045 PTO-892) and Wester et al. (WO 99/56558, PTO-892) in view of Letton et al. (5,306,516, PTO-892) and Dickson et al. (5,869,304, PTO-892).

Miettinen et al. disclose that sterol fatty acid esters such as fatty acid esters of β -sitostanol are useful in compositions for reducing serum cholesterol level. See abstract, col.1 lines 10-15, col.3 lines 45-50. Miettinen et al. also disclose that these sterol fatty acid esters compositions can be added to foods, such as at 3 to 6 % by weight to mayonnaise, at 10-20% weight to margarine, and sunflower, soybean, olive and corn oil, for the same purpose to reduce serum cholesterol level. See col. 4 lines 62-67 and Examples 2-5 at col.5-6. Miettinen et al. further disclose that fatty acids employed therein have approx 2-22 carbon atoms. See col.3 line 67 to col.4 line 1.

Wester et al. teach that fatty acid esters of phytosterols and phystostanols are known to be useful in compositions for reducing serum cholesterol level. See abstract, page 1-3. Wester et al. also disclose that these sterol fatty acid esters compositions can

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be added to foods, such as margarines, low-fat spreads, cheese spreads, butter, cooking oils and salads oils, or capsules for the same purpose to reduce serum cholesterol level. See page 4 lines 9-31. Wester et al. further disclose that particular sterol fatty acid esters compositions comprise a blend of less than 7% SFAs and more than 50% or 60% PUFA as fatty acid moieties. See claims 1-16.

The prior art does not expressly disclose particular sterol fatty acid esters compositions herein comprising more than 50%, 55-80%, or 60-70% of fatty acid moieties which are monounsaturated fatty acids (MUFAs) and less than 6%, 0.1-4%, or 0.5-2% of SAF moieties and 50% or less PUFA moieties. The prior art does also not expressly disclose a food product comprising these particular sterol fatty acid esters compositions at 5-30% weight.

Letton et al. disclose that particular mono- and/or di- unsaturated fatty acids such as oleic acid are preferred to be employed in shortening compositions therein containing polyol fatty acid esters because of their oxidative stability. See col.5 lines 36-38, col.6 lines 14-16, and col.9 lines 21-24. Letton et al. also disclose that fatty acid moieties (radicals) including unsaturated and saturated can be used broadly in mixture with each other in all proportions. See col.5 lines 44-55.

Dickson et al. teach that diets rich in saturated fatty acids (SFAs) are known to be associated with increased risk of coronary artery disease whereas monounsaturated fatty acids are known to be associated with decreased risk. See col.1 lines 20-23.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ more than 50%, 55-80%, or 60-70% of monounsaturated

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fatty acid (MUFA) moieties and less than 6%, 0.1-4%, or 0.5-2% of SAF moieties and 50% or less PUFA moieties in particular sterol fatty acid esters compositions herein, and prepare food products herein comprising these compositions at 5-30% weight.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ more than 50%, 55-80%, or 60-70% of monounsaturated fatty acid (MUFA) moieties and less than 6%, 0.1-4%, or 0.5-2% of SAF moieties and 50% or less PUFA moieties in particular sterol fatty acid esters compositions herein since the particular fatty acids, MUFA, are known to have higher oxidative stability than PUFA based on Letton et al. Therefore, one of ordinary skill in the art would have modified the compositions and foods of Wester et al. and Miettinen et al. by employing more than 50% of MUFA in order to make the compositions therein stable enough to be added into food products. Moreover, since MUFA are known to be associated with decreased risk of coronary artery disease whereas SFAs are known to be associated with increased risk according to Dickson et al., one of ordinary skill in the art would have preferred to employ more than 50% of MUFA to decrease risk of coronary artery disease or reduce serum cholesterol level in the compositions and foods of Wester et al. and Miettinen et al. Hence, both Letton et al. and Dickson et al. have provided the motivation to modify the compositions and foods of Wester et al. and Miettinen et al. by increasing MUFA to more than 50%, 55-80%, or 60-70% of MUFA moieties and decreasing PUFA 50% or less based on the prior art.

Further, fatty acid moieties including unsaturated and saturated can be used broadly in mixture with each other in all proportions in a composition to achieve

desirable physical properties according to Letton et al. Thus, one of ordinary skill in the art would have modified the known compositions to the instant compositions and food products because the optimization of amounts of active agents to achieve desirable physical properties is considered well within the skill of artisan, involving merely routine skill in the art.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
January 24, 2002


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